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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/271,411
Filing Date: March 17, 1999
Appellant(s): NORTHRUP ET AL.

Chun-Pok Leung
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed March 14, 2005 appealing from the Office action mailed June 9, 2004.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

HANDIQUE et al (US 6,130,098)

WILDING et al. (US 5,587,128)

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 45-50, 52-55, 57, 58, 60 and 62-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over HANDIQUE (US 6,130,098).

HANDIQUE teaches a one-piece polymeric (polysilicon) microscale device comprising a reaction chamber/region, and a transition region (transport channel) wherein the transition region is thermally isolated from the reaction chamber, and a separation region; e.g. electrophoresis module (col. 3, lines 57-64 and col. 4, lines 33-47, and Figures1-4), as in claims 45 and 54. HANDIQUE teaches several "valve" embodiments in his channels. He specifically teaches flow control with sealed valves wherein one type of valve is controlled by a diaphragm (as in instant claims 50 and 52) and another type is comprised of a meltable material wherein the valve is opened by heating (col. 6, lines 26-31 and col. 16, lines 41-61). HANDIQUE also teaches a microcapillary valve controlled by a bubble pump (col. 8, lines 23-37). In Examples 9

and 12 (col's 30-31), HANDIQUE specifically exemplifies devices with microcapillary and solder valves. HANDIQUE teaches that his devices may comprise one or more gel electrophoresis modules and at least one electrode, and teaches that standard gel electrophoresis occurs in a channel (col. 21, lines 35-68). HANDIQUE teaches a light source and detector (optics) for detecting separated sample components (col. 21, line 60-col. 22, line 3), as in instant claims 46 and 48. HNADIQUE specifically teaches viewing of his reaction via a glass or quartz "window" in his reaction chamber (col. 27, lines 60-62). HANDIQUE teaches that his device may comprise a biologically compatible heating element (col. 27, lines 58-68), as in instant claim 46. HANDIQUE teaches side channels and means for adding or removing fluid in side channels, including an inlet port (col. 14, lines 24-44 and Figure 3), as in instant claims 49 and 53. HANDIQUE teaches that his device comprises standard electrical pads; i.e. electrodes (col. 13, lines 53-59 and Figure 4B), as in instant claims 57 and 58. HANDIQUE teaches several methods of using his device comprising inserting a sample in a reaction chamber wherein the reaction chamber is thermally isolated from a transition and separation region (Example 5, col's 27-28) and electrophoretically separating and detecting reaction products (col. 21, lines 53-68), as in claims 60,64, and 70. HANDIQUE's reaction is a nucleic acid based amplification reaction (col. 27, lines 34-42), therefore his detected products (Figure 10) necessarily comprise amplified nucleic acid, as in instant claim 62. HANDIQUE discloses use of a pump and/or electrodes to move liquids through channels and into a separation chamber (col. 7, line 53-col. 8, line 44), thus teaches "electrophoretic injection" into a separation region, as in instant claim

63. HANDIQUE's reaction chamber is heated (col. 28, lines 24-36), as in instant claim 65, and HANDIQUE teaches various methods of introducing and controlling fluid flow in his device (col. 30, line 18-col. 31, line 55), as in claims 66-69. HANDIQUE specifically teaches opening and closing valves to control flow through side channels into a main (e.g. reaction) channel or chamber (col. 30, Example 9).

HANDIQUE does not specifically teach "at least two electrodes" as recited in part (b) of claim 45, nor injecting a sample "plug" into a separation region, as recited in step (d) of claim 60.

It would have been obvious to one of skill in the art at the time of invention to have formulated the device of HANDIQUE with "at least two electrodes", as suggested by the teaching for multiple electrical pads of HANDIQUE, where the motivation would have been to separate samples components using electrodes, as suggested by the electrophoretic separation taught by HANDIQUE, above. It would further have been obvious to have injected a sample as a "plug" in the method of HANDIQUE where the motivation would have been to improve electrophoretic resolution, as taught by HANDIQUE as being a desired result (col. 21, lines 37-51).

Claims 45-50, 52-55, 57, 58, 60, and 62-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Handique et al. (6,130,098), taken in view of Wilding et al. (P/N 5,587,128), or, alternatively, Wilding et al. (5,587,128), taken in view of Handique et al. (P/N 6,130,098).

HANDIQUE teaches and makes obvious the claimed device and method, as set forth above. HANDIQUE teaches differential heating of various elements of his device, thus necessarily teaching that portions of his device are thermally isolated. However, HANDIQUE does not teach an embodiment wherein the device itself is designed or constructed for thermal differentiation between areas.

WILDING teaches a device and use of the device in a PCR method similar to that of HANDIQUE (col. 3, line 47-col. 4, line 36), teaches thermal cycling and application of different temperatures to different regions of the device (col. 7, lines 4-21), teaches addition of reagents through an inlet port, which may be sealed, and teaches means for moving fluid between sections (col. 7, lines 4-22 and lines 57-67). WILDING teaches designing his device such that a transition region allows for cooling of a sample upon transport through the transition region; i.e. teaches thermal isolation via design of the device (col. 17, line 55-col. 18, line 10).

It would have been obvious to one of ordinary skill in the art at the time of invention to have constructed a device such as that of either HANDIQUE or WILDING to allow for either external thermal differentiation between sections of the device, as taught by HANDIQUE or to have designed the device to comprise thermally differentiated areas, as taught by WILDING, where the motivation would have been to regulate temperature of different reactions, as taught by both HANDIQUE (col. 22) and WILDING (col. 18).

(10) Response to Argument

A. In response to the argument that HANDIQUE does not teach a valve in a region connecting a reaction chamber to an electrophoresis chamber, it is noted that HANDIQUE teaches and exemplifies several kinds of valves, as set forth in the rejection above, and specifically teaches flow control with sealed valves (col. 16, lines 4-65), teaches how to make valves blocking fluid flow in channels (col. 30, Example 9), teaches that his invention comprises a channel in liquid communication with a reaction region via a transport channel and separated by a barrier, wherein liquid may be transported using flow-directing means, specifically heat (col. 4, lines 33-47). HANDIQUE further teaches that fluid flow may be restricted in connecting channels via a heat-sensitive valve (col. 6, line 61-col. 7, line 12) or via a capillary valve (col. 8, lines 23-27). Thus, HANDIQUE teaches that any channel may comprise a valve to restrict or control fluid flow. As he also specifically teaches that his reaction chamber is connected to a channel via a transport channel, and teaches that the "other" channel may be a separation channel, the totality of HANDIQUE's disclosure teaches valves in a "transition channel" to control flow between regions of his device. In response to the argument that there are no valves in Figure 1 of HANDIQUE, it is noted that a reference is relied upon for the totality of its teachings. Figure 13 specifically exemplifies a valve in a channel. In response to the argument that Figure 13 shows a "different device", it is noted that all Figures represent different embodiments of HANDIQUE's device and are not disclosed as being exclusive of one another. As set forth above, HANDIQUE clearly

teaches a variety of valves and teaches that any of them may be used to control or restrict flow in ANY channel. HANDIQUE does not teach that his valves must be used only in particular positions in his device. HNADIQUE teaches that microdroplets (fluid) may be moved along his channels using heat and/or pressure (col. 14, line 14-col. 15, line 19). As these embodiments require control of internal pressure in HANDIQUE's device, appellant's arguments with regard to "high internal pressure" and diffusion are not persuasive. In response to the argument that HANDIQUE "teaches away" from valves, it is admitted that HANDIQUE teaches an embodiment of his device which does not require valves. However, this is not a teaching that his device CAN NOT comprise valves nor that his device would not be enabled (i.e. would not "work") if valves were present. Further, and as set forth above, HANDIQUE clearly teaches and exemplifies several different types of valves for use in his device, including a diaphragm controlled valve, a heat controlled valve, and a microcapillary valve. Thus, appellant's arguments that HANDIQUE teaches away from valves is not persuasive.

B. In response to the argument that HANDIQUE fails to teach or suggest a step of opening a valve and injecting a sample into a separation region, it is noted that HANDIQUE teaches at least two valves which open and close, specifically teaches opening of a heat actuated valve in order to allow fluid flow from one channel to another (col. 30, Example 9), and teaches connection of a reaction chamber to a separation chamber via a channel, as admitted by appellant to be shown in Figure 1. It is admitted, as set forth above, that HANDIQUE does not specifically teach "injection" of a sample

plug into the separation area. However, HANDIQUE does specifically teach movement of fluid (i.e. samples) along channels to desired locations, and the examiner maintains, also as set forth above, that HANDIQUE suggests and motivates a step of injecting a sample plug. As a closed valve (e.g. the solder of HANDIQUE) must necessarily be opened to allow fluid flow, the examiner maintains that the totality of teachings of HANDIQUE for control of fluid flow in channels between areas of his device and control of fluid flow via valves does suggest the contested method step.

The remainder of the arguments with regard to HANDIQUE are identical to those set forth with regard to the device, above. The examiner finds these arguments to be nonpersuasive for the same reasons set forth above.

C. Appellants arguments with regard to HANDIQUE have been addressed above. For the same reasons as those set forth above, appellant's arguments are not persuasive. In response to the argument that WILDING fails to remedy the argued deficiencies of HANDIQUE; i.e. a valve in a transition region, it is noted that HANDIQUE does teach this limitation, as set forth and maintained above.

D. Appellants arguments with regard to a missing method step in HANDIQUE have been addressed above. For the same reasons as those set forth above, appellant's arguments are not persuasive. In response to the argument that WILDING fails to remedy the argued deficiencies of HANDIQUE; i.e. a device with a valve in a transition

region, it is noted that HANDIQUE does teach this limitation, as set forth and maintained above.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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PRIMARY EXAMINER
7/6/06

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